Dr Andrew Thomson – RCOG Recommendations/Audit

So much of what I'm about to tell you, you may have already heard, perhaps more articulately this morning. So we were asked to provide any conflicts of interest, so I'm currently co-chair of the guidelines committee and as such I'll be defending the college guideline.

So wee bit of background that you all know. GBS is commonly carried in the gut and genital of healthy people. If we look at different papers different sources we see that quite variable numbers. It's estimated in the UK the carrier rate is between 25-28%. We know that GBS can be passed from pregnant women to their babies during labour. Again numbers that we've heard more recent data today, approximately 0.36-0.41 babies per 1,000 live births contract some form of GBS illness. In the majority of cases, this is a mild illness. And we heard from Dr O'Sullivan earlier on that I think the figure she showed was 0.52 and I think the slide was really quick but I'm sure I noticed in Scotland it was 0.24 per 1,000. It was really quick but I'm sure I noticed that. Whilst the majority of illnesses in neonates is mild, unfortunately some babies will become seriously unwell with GBS causing things like meningitis, pneumonia and septicaemia. And approximately 25 babies a year in the UK sustain serious disability, things like cerebral palsy, deafness, blindness and learning difficulties. And we heard this from earlier speakers this morning. Tragically as you now 40 babies in the UK each year - approx. 40 babies - don't survive GBS infection.

As mentioned in the introduction, I'm not employed by the college or the NSC, I'm a full time clinician in a DGH in the west of Scotland and stories like this one here from the Metro I find incredibly sad and upsetting. It's upsetting for everyone involved, it's upsetting for the woman and also it's upsetting for the people who look after these women.

Strategies to reduce EOGBS disease in the neonates. This was a paper from 2013. It doesn't mention vaccination; it doesn't mention giving all pregnant women antibiotics when they give birth. It mentions antenatal screening for maternal colonisation, usually between 35 and 37 weeks gestation. And we heard earlier that that strategy has been employed pretty widely worldwide, identifying risk factors for EOGBS in pregnancy or during labour and women identified to have risk factors are then given intrapartum abx prophylaxis. Or this strategy here a combination strategy where a culture is taken at 35-37 weeks gestation and women with both GBS colonisation and one or more of the established risk factors for GBS receive intrapartum antibiotic prophylaxis.

Straight to the point. The RCOG GTG guideline initially published in 2003 and revised in 2012 concluded that routine bacteriological screening of all pregnant women for antenatal GBS

carriage is not recommended. So we grade our recommendations and this is given as a grade D recommendation and the evidence for that is given underneath and its evidence level 4. And you see what is that recommendation based on. Essentially that is based on expert opinion. It's not based on good studies; it's not based on good science. It's based on a group of experts coming to that conclusion. And in this particular case the group of experts were from the National Screening Committee. In the supporting text here we say "until it is clear that antenatal screening for GBS carriage does more good than harm and that the benefits are cost effective (I don't like cost-effective, we try now to avoid cost effectiveness being mentioned in our guidelines but it says it here), the NSC does not recommend routine screening in the UK." "Initiating national swab based screening for antenatal GBS carriage would have a substantial impact on the provision of antenatal care within the UK. Major organisational changes and new funding would be required to ensure an equitable and quality assured service." Those are the words used in the more recent version of the guideline.

We do recommend the administration of intrapartum antibiotics based on the following risk factors - GBS bacteriuria in the current pregnancy, GBS detected on a vaginal swab in the current pregnancy whereas Prof Steer says, the woman complains of some discharge or some thrush and we take a swab, and the report shows GBS, Suspected chorioamnionitis, broad spectrum intrapartum antibiotic prophylaxis is recommended with GBS cover, a pyrexia in labour over 38 Celsius (we do not mention epidurals) and once again intrapartum antibiotics with GBS cover is recommended. And a previous baby with neonatal GBS disease. And each of these risk factors has been eloquently critically appraised by Prof Steer.

The RCOG advises against the following - routine screening all pregnant women for antenatal GBS carriage. We advise against testing for GBS or the administration of intrapartum antibiotics to women in whom GBS was detected in a previous pregnancy. I am a clinician working in a DGH in the west of Scotland. It's not uncommon for pregnant women to say to me, will I be given antibiotic again since you found the GBS last time. I find it very difficult, and I find it very awkward. I try to explain to them that the college guidelines advise against this practice. We have a discussion and the management is based on an individualised ... let's move on.

Antenatal treatment - the College advises against antenatal treatment with Benzylpenicillin if GBS is detected and advises against GBS specific antibiotic prophylaxis in these situations - undergoing planned Caesarean section with intact membranes, prelabour rupture of membranes unless there is known GBS colonisation, established preterm labour unless there is known GBS colonisation, and preterm prelabour rupture of membranes. And when we look through the various guidelines from NICE, it's my understanding that - I must confess I find it difficult navigating some of the lengthy NICE guidelines - but I believe there's a discrepancy between our guidance and the guidance from NICE and it's never good to have inconsistencies in national guidelines. That's never good.

So, what has been the impact of risk based guidance? No benefit has been shown from studies in the UK, from the Netherlands, whilst benefit has been shown from Denmark and New Zealand. In England and Wales, a study published in 2013 showed rates of EO neonatal disease fluctuated but showed a general rise - and we've heard this from other speakers earlier on. Between 2000-10 from 0.28 to 0.41 per 1,000 live births. That's very difficult to understand. It's difficult to understand because we know that even if we're not doing this well, we are giving abx to some women. Are we giving it to completely wrong women? Do the abx not work? Or are the background rates going up as was suggested from previous speakers?

In the Netherlands, the introduction of preventative guidelines for invasive GBS in 1999 did not reduce the incidence of disease in infants and the authors of that paper in 2014 Bekker et al concluded that it was time to introduce a screening programme.

This an old paper - 2004 from Denmark and this shows an initially very high level of GBS, it was 1 it was up to 2 cases per 1,000 live births back in 1993. And then following the introduction of a risk based guidelines, the instance of EOGBS decreased significantly in Denmark. They concluded probably because of measures in pregnancy and during birth. So some benefits there down to a low level of about 0.15, 0.2 per 1000. But that's old data.

More recently, 2015 study from NZ. An introduction of a risk based strategy as a single national policy to reduce EOGBS occurred in 2004 in NZ. The first cohort, there were 2 separate cohorts here. The first cohort 1998-1999, the incidence of EOGBS was 0.5 per 1,000 live births. Following the introduction of the risk based strategy in 2004, the second cohort 2009-2011 showed the incidence of EOGBS to have fallen to 0.23 per 1,000 live births. The authors conclude 10 years after a similar survey and 5 years after promoting a single risk based prevention protocol nationally the incidence of EOGBS disease in NZ has more than halved.

So why have the RCOG guidelines failed to improve outcomes? This was a paper published in the BJOG earlier this year from Northern Ireland where the incidence and I understand the incidence of EOGBS disease is pretty high and in this paper - I think it's a wee bit flawed on looking at the numbers - the incidence was pretty high here. The incidence of EO disease in Northern Ireland was 0.57 per 1,000 live births. 24 neonates who developed EOGBS had one or more identifiable risk factors. But only 11 of these 24 cases received abx. So 24 had risk factors, 24 should have received abx but only 11 received the abx. And the authors say that at best guideline adherence was 50-70%. To me at best guideline adherence was less than 50%; I don't know where they got the 70% from, with respect to them.

NZ we mentioned this already, we said the first cohort was 0.5 per 1,000 and the second cohort had reduced to 0.23. But even in this second cohort there were 16 cases where a maternal risk factor for EOGBS was present but only five of these 16 received abx. The authors said that opportunities remained to reduce the rate further. So whilst they did a

pretty good job, they could do better. They said until more effective strategies become available, it seems appropriate to consolidate and improve the current approach through on-going education regarding risk factors and appropriate abx for intrapartum antibiotic prophylaxis and repeat audits. We must keep repeating audits to monitor our practice. So they're saying, they did a good job, they could do better and they're concluding they should stick with the current strategy for improving what they're doing.

Alan's already mentioned these audits. The RCOG has conducted a number of audits looking at GBS over the years. One back in January 2007, the more recent one from March this year. And the second part of the more recent one will be published hopefully in the next month or two. The first audit - what were its aims? The three aims were to carry out an international comparison and evaluation of the existing national guidelines on the prevention of EOGBS disease. Secondly to assess the consistency of the local clinical protocols provided by NHS and independent sector obstetric units in the UK and thirdly to evaluate practice on preventing neonatal GBS disease against the RCOG guidance and to assess whether it has changed since the surveys were carried out in 1999 and 2001.

A number of recommendations that have been lifted entirely from that document - essentially what it's saying here is that obstetric units should continue to offer intrapartum antibiotic prophylaxis to women with risk factors in accordance with our guidelines, that a local protocol or guideline should be readily available to staff and units should ensure its interpreted and implemented consistently. Units should ensure that their protocols are up to date and consistent with national guidelines albeit adapted for local context. Some advice for us when revising the GTG, care should be taken to ensure
that recommendations are unambiguous and comprehensive. There continues to be confusion about our recommendations. The revised RCOG GTG should include clearly defined audit criteria, something that we do now for all of our guidelines. And it mentioned that there was an urgency to have an appropriately undertaken research to fill the current gaps in the evidence base on which strategies to identify women for IAP are most effective in preventing disease. So we need to research. We've heard about the risk factors that we recommend, that are recommended in our guideline. And perhaps some of the evidence advocating those risk factors has been updated since the guideline was more recently published, and we need to take that into account.

The second audit that Alan mentioned was to investigate the implementation of the revised version of the GTG, the 2012 version, in obstetric units in the UK. To examine variation and preventative care for EOGBS in the UK, and to identify areas for improving guideline adherence and practice. The same sort of themes.

Alan has gone through these recommendations very briefly. The report recommended that local guidelines on the prevention of EOGBS should reflect the national guidelines and be fit for purpose. And many of you are probably thinking but they will say that - the RCOG will tell you to use the RCOG guidelines. Information on GBS provided to patients should be

reviewed regularly and reflect national recommendations. We don't want any inconsistencies, it leads to confusion. Reviews of practice on preventing EOGBS should be regularly undertaken and inconsistencies in practice and knowledge should be challenged.

For a while, for a couple of years, infection became the big thing in our unit - infection as in hospital-acquired infections. And we created I'm sure we have done over the whole of the UK but in Scotland we created infection champions. You cannot walk onto - well, first of all you shouldn't walk onto a ward without using the alcohol gel. But if you're really busy and forget because you've just used it 10 seconds ago, any other member of staff regardless of pay scale, anyone can come up to you and say "Excuse me but please go and wash your hands before you come into this ward." And so they should be able to do that. ~Similarly here we need to heighten the awareness of the GBS recommendations and the GBS guideline because it's not a priority at the moment.

Our college in its press release for the more recent audit said, "This report highlights the need to improve the consistency of preventative care in EOGBS in UK maternity units as it has identified marked variations in some areas of practice."

GBSS, the organisers of today, in response to the 3.7% of units who have reported universal screening of all pregnant women said, "Instead of calling for stricter adherence to the guidelines, which was the moral of the RCOG audit story, is it not more appropriate for the guidelines to catch up with the practice of screening that is already in play for these progressive units." I would suggest they're not progressive personally.

I'm going to stop for one small minute and I'm going to tell you a small story. It's not a very good story. So Mrs Smith goes to see her obstetrician. The obstetrician says

"Hello Mrs Smith. I've got the results of your blood tests. You're anaemic. Our guidelines recommend you take some iron tablets. One tablet 3 times a day and we'll recheck your blood again in 4 weeks."

"OK doctor, sounds good. One tablet 3 times a day. I'll make sure I do that." [Thinks: There's no way I'm going to take iron tablets. I had them in my last pregnancy and they made me really constipated.]

4 weeks later: "Hello again Mrs Smith. Unfortunately your repeat blood tests have shown no improvement in your blood count."

"Oh that's disappointing doctor. Why do you think there's been no improvement? Oh quite clearly the iron tablets aren't being absorbed from your bowel. We'll need to admit you to the ward and give you the iron into your vein through a drip.

"OK doctor, sound good. You'll maybe need to think about changing that useless guideline that recommended iron tablets."

[Thinks: "What a rude woman, but maybe she's right. Maybe the guideline does need to be changed."]

What's the moral of the story? Never trust pregnant women to take their tablets? No, that's not the moral of the story. The moral of the story, if a guideline isn't implemented properly and fully then don't be surprised if there's no improvement in clinical outcomes. If a guideline isn't being implemented properly and fully, then consider what needs to be done to achieve this. Guideline implementation is a key element of clinical governance. In Scotland we've got Health Care Improvement Scotland. If we decided to change from risk based to screening, we would be visited by Health Care Improvement Scotland who would audit our practice, tell us where we're going wrong and tell us to correct that, not to change the practice.

A lot has been said about GBS screening. A lot has been written and I am getting the impression as Chair of the Guideline Committee and therefore kind of responsible for the guideline. I'm concerned that two camps have evolved. The case for screening and the case against screening and continuing with the current risk based approach. And it seems to - and this is not disrespectful honestly - it seems to be the same people who are writing the same things in a very argumentative way all the time. Probably one of the most intellectual and insightful and persuasive articles I have ever read on the subject was this one from the BJOG of February 2015. If you read nothing else, or take nothing else away from me, please look this out and read it. For both sides of the argument, it's fantastic. It's really really good. I found myself agreeing with this side. And I found myself agreeing with this side. And that is what we should be doing. We should be thinking how we move forward here. This side incidentally is Prof Steer. I am of course going to quote from the other side, because that's why I'm here today, from Peter Brocklehurst. What he says, "Most of our efforts are directed at auditing and monitoring the offer and uptake of screening programmes using clinical governance processes to ensure adherence to the programme with rigorous quality control." And I think of first trimester screening, I think of quality control, I think of the amount of work and effort that goes into that. We don't put any of that work and any of that effort into the way we try to prevent GBS. What he's saying - should we not have this same when we have a policy of not offering screening? Should we not invest some time and money at looking at the current policy to try and implement it so that it does make a difference? Should trusts audit their own practice to ensure adherence to national policy? And what role does the CQC have in ensuring that trusts do this? So in Scotland we don't have the CQC, we've got Heath Care Improvement Scotland for our Health Boards, but they do have a role. They would not let us implement screening. Adherence to national policy whether that is to screen or not to screen is important when making sure that scarce resources are used most effectively.

I'm going to finish, and to finish I'm going to say that the UK strategy to reduce the EOGBS is based on the identification of risk factors in pregnancy or during labour. Alan mentioned that the NSC are currently reviewing the evidence. They say they will do this 2015/16. The process to revise the relevant RCOG GTG is now underway and appears on the agenda for our next meeting in 2 or 3 weeks' time. It takes us 3 years to revise a guideline, which is too long. We now have a mechanism in place where we can produce, update or revise a guideline in one year and if the evidence was compelling that we needed to change the practice, then we could revise a guideline in one year or less.

Failure to implement guidelines is a clinical governance issue and deserves greater attention. And in this college our guideline committee has been tasked with developing tools to improve guideline implementation. Thank you